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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,014	07/10/2001	Wei-Sing Chu	2313-116	8862

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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,014	CHU, WEI-SING	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70,72-79 and 92-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70,72-79 and 92-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2005 has been entered.

Response to Amendment

2. Applicant's amendment of claims 70, 72-79 and newly claims 92-97 are acknowledged and has been entered.
3. Claims 70 and 72-79 and 92-97 are pending.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 70, 72-79 and 92-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 70 recites a system for fixation an processing a tissue sample in the preamble, but claims a tissue sample in the body. It is not clear as to whether applicant is claiming a system or a combination of a system and a tissue sample.

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7. (Claims 72-79 and 92-97 are vague because they depend from claim 70, which is vague for the above reason.)

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 70, 72-79, 96 and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup et al [US 5,639,423].

With respect to claim 70, Northrup et al teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer (ultrasound generator) (column 7, lines 29-35) and Lamb-wave sensor (ultrasound sensor) in a solution in a chamber (reaction chamber) (column 7, lines 29-35), where the transducer is located on a thin film wall of the chamber (claims 1, 3). Northrup et al further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48). Northrup et al also teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (central processing unit) (column 4, lines 40-45). A tissue sample is disclosed at column 5, line 60). Northrup et al

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further teach that the reactor may be used to process fixed cells or tissues for PCR and subsequent techniques (column 5, lines 42-61).

The limitation that the central processing unit adjusts a frequency or an intensity of said ultrasound in response to signals from the first and second sensors to regulate the ultrasound generator and adjusts a frequency or intensity of ultrasound in response to the signals from the first and second sensors is regarded as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Since Northrup et al teach that the integrated microelectronic devices are capable of processing and storing detection signals so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45), the microelectronic devices would be capable of performing the function of the CPU.

With respect to claims 72-74, the density is measured (column 11, lines 45-47) by monitoring the wave characteristics using Lamb-wave sensors (column 11, lines 39-42).

10. With respect to claim 75, detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45).

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11. With respect to claim 76, Northrup et al teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45).
12. With respect to claim 77-78, the transducer produces Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).
13. With respect to claim 96, a solution is capable of being pumped into the reaction chamber as a first solution is pumped out of the chamber and into the detection chamber (column 7, lines 35-37).
14. With respect to claim 97, a used solution is pumped to a waste receptacle (column 7, lines 35-37 discloses a channel equipped with a pump, wherein the channel connects the reaction chamber with a detection chamber, which is considered the claimed waste receptacle.)

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423], in view of Chu [5,958,341].

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Northrup et al. teach the invention substantially as claimed (see above with respect to claim 70). Northrup et al. teach that the device can be used to process fixed cells as well as tissue samples (column 5, line 60). However, Northrup et al. do not teach that the sample is immersed in a solution of 10% formalin, alcohol, xylene or parafin.

Chu teach preparing a tissue sample with 10% formalin embedded in paraffin and later treated with xylene and ethanol in order to fix the tissue (column 18, lines 5-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to immerse the tissue sample in the solutions as taught by Chu in the Northrup et al. invention because Chu teach that these solutions are used in preparing tissue samples, particularly in fixing.

Response to Arguments

17. Applicant's arguments with respect to claims 70-79 have been considered but are not persuasive. Applicant argues on page 6 that Northrup does not disclose or even suggest a system in which ultrasound is used to process or fix tissue samples such that they retain their normal histology or pathology, nor does it suggest a system in which an ultrasound generator and a tissue sample are immersed in a solution in a reaction chamber. With respect to claims 70-79 and new claims 96-97, Applicant does not claim these limitations. With respect to new claims 92-95, as described above, Chu teaches the motivation to immerse a tissue sample in the solutions claimed by Applicant.

In response to applicant's argument that the ultrasound is used to process or fix tissue samples such that they retain their normal histology or pathology, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and

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the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

18. It should also be noted that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Nelson Yang
Patent Examiner
Art Unit 1641

Christopher L. Chin
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3/3/06